In the United States Court of Federal Claims

JANIE MILLER, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	No. 18-vv-327 Filed Under Seal: September 3, 2024[1] Publication: September 20, 2024

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MEMORANDUM AND ORDER[2]

Pending before the Court is Petitioner Janie Miller's Motion for Review of the Special Master's March 7, 2024 Decision denying her Petition for Vaccine Compensation brought under the National Vaccine Injury Compensation Program. This action involves long-term treatment endured by the Petitioner that evokes sympathy from the Court. Nevertheless, this Court must adjudicate cases based on application of the law, even when such an approach might lead to a disappointing or unfulfilling result for those involved. For the reasons discussed further below,

[1] On September 3, 2024, this Court issued a sealed version of this Memorandum and Order. ECF No. 128. The parties did not propose redactions by the deadline to do so. Accordingly, the sealed and public versions of this Memorandum and Order are identical, except for the publication date and this footnote.

[2] Citations throughout this Memorandum and Order reference the ECF-assigned page numbers, which do not always correspond to the pagination within the document.

the law requires this Court to rule in favor of the Respondent. Accordingly, Petitioner's Motion for Review is **DENIED**.

BACKGROUND

I. Factual Background[3]

On October 1, 2016, Petitioner, then a 64-year-old woman, received a seasonal influenza vaccine, "Fluvirin 2016-17." *See* Petition for Vaccine Compensation (ECF No. 1) (Petition or Pet.) ¶ 1–3. On October 12, 2016, Petitioner noticed a sore on her right foot, which became a rash that spread to both feet. Ex. 10 (ECF No. 37-7) at 8 (noting onset of rash on feet as "11/9/2016"); *see* Pet. ¶ 3. On November 11, 2016, APRN (Advanced Practice Registered Nurse) Lindsay Meggas noted the bilateral rash and swelling of feet and referred Petitioner to the Emergency Room (ER); there are no medical records in the record supporting that Petitioner in fact visited the ER. Ex. 10 at 8–9; *Miller v. Sec'y of Health & Hum. Servs.*, No. 18-327V, 2024 WL 1340598, at *1 (Fed. Cl. Spec. Mstr. Mar. 7, 2024); *see generally* Ex. 3 (ECF No. 8-4); Ex. 4 (ECF No. 8-5).

On November 14, 2016, Petitioner saw Dr. Douglas Thompson about the rash, which was noted as having been present for "5 days." Ex. 4 at 1, 3. Issues addressed included "Tiredness," "High cholesterol or triglycerides," and "Type 2 diabetes mellitus with hyperglycemia, without long-term current use of insulin."[4] Ex. 4 at 1. On November 18, 2016, Dr. Michael Chen, a

[3] Petitioner acknowledges in her Memorandum of Objections that "[t]he primary facts as established by witnesses and documents are not in major dispute." Petitioner's Memorandum of Objections (ECF No. 125-1) (Memorandum of Objections or Obj. Mem.) at 2.

[4] The Special Master also noted that Petitioner was encouraged to "continue to check her blood sugar in the mornings before eating," and that her other laboratory studies produced "normal results." *Miller*, 2024 WL 1340598, at *1 (citing Ex. 4 at 1, 4–5). Petitioner maintains that prior to vaccination, she was "healthy with no underlying disease or infection and was not taking any prescription medication." Mot. at 1.

dermatologist, performed a punch biopsy on Petitioner, and Dr. Julio Cruz, a dermatopathologist, found that the "findings are strongly suggestive of leukocytoclastic vasculitis" (LCV). Ex. 4 at 40.[5] Petitioner was therefore prescribed prednisone. Ex. 3 at 1 (noting, on December 11, 2016, that Petitioner "has been on Prednisone for about one month for vasculitis"); Affidavit Pursuant to § 11(c)(1) (ECF No. 1-2) (Pet'r Aff.) ¶ 4. Subsequently, Petitioner developed further health issues, which she relies upon to attempt to demonstrate that her injury resulted from LCV and ultimately, the vaccine.[6]

On December 10, 2016, Petitioner fainted while walking in a parking lot. Pet. ¶ 4. She was then admitted to the hospital after an emergency room visit to evaluate her syncope. Ex. 3 at 4. The LCV legions were present but healing. *Id.* at 55. On December 13, 2016, while Petitioner was still admitted, a rheumatologist, Dr. Kevin Schlessel, noted that "there is no obvious etiology [to Petitioner's LCV] and no evidence to suggest systemic vasculitis." *Id.* On January 12, 2017, Petitioner was admitted to the hospital again following a rheumatology appointment because an ultrasound revealed extensive acute bilateral deep vein thrombosis and acute pulmonary embolism (DVT/PE). *Id.* at 266. She was discharged on January 20, 2017, after placement of an inferior vena cava (IVC) filter. *Id.* at 258, 384.

On February 27, 2017, a radiologist noted her DVT/PE "occurred in the setting of an acute inflammatory condition secondary to [LCV] and elevated BMI." Ex. 4 at 41. On March 10, 2017, Petitioner's IVC filter was removed. Ex. 7 (ECF No. 23) at 4. As of June 2017, Petitioner was

[5] All experts accept Petitioner's LCV diagnosis. *See Miller*, 2024 WL 1340598, at *1 n.3 (citing Ex. 23 at 2–3; ECF No. 79-1 (Ex. A) (Fadugba Report or Fadugba Rep.) at 6; ECF No. 80-1 (Ex. C) (Antiochos Report or Antiochos Rep.) at 2).

[6] The Special Master summarized the remaining records but specified they "are largely not relevant to determining whether the flu vaccine caused [Petitioner's LCV]." *Miller*, 2024 WL 1340598, at *2.

still on Xarelto for treatment of her blood clots, and she remained on anticoagulation and steroids treatments one year after her LCV diagnosis. *See* Ex. 4 at 49; Pet. ¶ 7; First Amended Supplemental Expert Report (ECF No. 72) (Shoenfeld Report or Shoenfeld Rep.) at 6. On December 5, 2017, Petitioner's radiologist noted, "Even though the PE/DVT occurred in a setting of an inflammatory process, the PE/DVTs were extensive." Ex. 4 at 22. Petitioner was recommended for cancer screening but declined. *Id.* at 23 ("I don't want to have that.").[7] Petitioner must remain on blood thinning therapy for the rest of her life due to the scarring and blood clots remaining in her right leg. Pet. ¶ 8; *see* Ex. 4 at 22–23.

II. Procedural Background

On March 5, 2018, Petitioner filed her Petition for Vaccine Compensation, alleging she had developed LCV, which further developed into DVT/PE, as an adverse effect of a seasonal influenza vaccination she received on October 1, 2016. Pet. ¶¶ 2, 3, 5; *see also* Pet'r Aff. ¶¶ 3, 4, 7. On March 9, 2018, Petitioner filed Exhibits 1–4. ECF Nos. 8-1–5. On January 24, 2019, Petitioner filed an Amended Index in support of her Petition that included Exhibits 5–7. ECF No. 23. On April 11, 2019, Respondent filed its Rule 4(c) Status Report. Respondent's Rule 4(c) Report (ECF No. 27) (Rule 4 Rep.).[8] On July 19, 2019, Petitioner filed Exhibits 8–22. ECF No. 37. On August 19, 2019, Respondent supplemented its Rule 4(c) Status Report, stating that it was satisfied Petitioner had provided sufficient evidence regarding onset and to satisfy the severity

[7] During a visit with Dr. Carolyn Rebecca Bullock on July 14, 2016, Petitioner also declined a colonoscopy and mammogram. Ex. 4 at 53; *see Miller*, 2024 WL 1340598, at *1.

[8] Respondent contended that: (1) Petitioner failed to provide adequate documentation to support that she received the influenza vaccine; (2) Petitioner failed to provide a theory explaining how the influenza vaccine can cause LCV or that it did; and (3) it was unclear whether Petitioner met the severity requirement given that she failed to provide evidence that her DVT/PE were sequelae of LCV or that she suffered it for more than six months post-vaccination. Rule 4 Rep. at 5.

requirement, but that it was not satisfied Petitioner had provided sufficient proof of vaccination. Respondent's Status Report (ECF No. 40) at 1. In his August 29, 2019 Order, however, the Special Master refuted Respondent's contention, noting that he had explained at a prior status conference that "the Kroger record of vaccination, together with petitioner's personal calendar entry showing that she was going to receive the vaccine on that day, constitute[d] preponderant evidence of the vaccination." Order, dated Aug. 29, 2019 (ECF No. 41) at 1–2.

On September 9, 2020, after prior failures to secure an expert, Petitioner informed the Special Master that Dr. Yehuda Shoenfeld would serve as her expert. Petitioner's Third Status Report on Medical Expert (ECF No. 57) at 2–3. On September 18, 2019, the Special Master provided draft expert instructions, which became "Final Expert Instructions" on October 10, 2019, after no party lodged an objection. *See* Order, dated Sept. 18, 2019 (ECF No. 43); Order, dated Oct. 10, 2019 (ECF No. 44) at 1; *Miller*, 2024 WL 1340598, at *3.

On October 22, 2020, Petitioner filed Dr. Shoenfeld's first expert report—Exhibit 23. ECF No. 60. On January 14, 2021, Petitioner filed Dr. Shoenfeld's Supplemental Expert Report and Revised References—Exhibit 24. ECF No. 64.[9] On February 3, 2021, Petitioner filed its First Amended Supplemental Medical Expert Report, Referenced Medical Literature, and Revised Exhibit List—Exhibit 25. ECF No. 65-1. The following were attached to the amended report: nine medical literature references (ECF Nos. 65-2–10); and Dr. Shoenfeld's C.V., listing his published articles (ECF No. 65-11). On February 23, 2021, Petitioner filed her final expert report—Exhibit 26, replacing all prior, previously-filed versions of the report.[10] *See* Shoenfeld

[9] On November 12, 2020, the Special Master held a status conference and issued an order directing Petitioner to file an expert report conforming to the October 10, 2019 Instructions. Order, dated Nov. 12, 2020 (ECF No. 61) (Order to Supplement).

[10] On February 4, 2021, the Special Master issued an order explaining that, at a status conference the day prior, he had notified Petitioner's counsel that Dr. Shoenfeld did not address items (2)–(6)

Rep. at 2 ("This report is intended to replace prior reports."); *see also* Order for Submissions in Advance of Potential Adjudication (ECF No. 95) (Feb. 16, 2022 Order) at 2 ("Dr. Shoenfeld's reports are exhibits 26 [ECF No. 72] and 28 [ECF No. 90-2]."); *id.* at 2 n.1 ("Dr. Shoenfeld also presented reports filed as exhibits 23 [ECF No. 60-1], 24 [ECF No. 64-1], and 25 [ECF No. 65]. These three reports are very similar to each other. Dr. Shoenfeld intended that his February 22, 2021 report replace previous reports. Exhibit 26 at 2.").

On July 10, 2021, Respondent filed the Report of its expert, Olajumoke Fadugba, M.D. Fadugba Rep. Dr. Fadugba's expert report included 15 medical literature references. ECF Nos. 79-2–16 (Ex. A-1–15). Respondent also included Dr. Fadugba's C.V. ECF No. 79-17 (Ex. B). On July 13, 2021, Respondent also filed the report of its expert, Brendan Antiochos, M.D. Antiochos Rep. Dr. Antiochos' expert report included 10 medical literature references. ECF Nos. 80-2–11 (Ex. C-1–10). Respondent also included Dr. Antiochos' C.V. ECF No. 80-12 (Ex. D).

On December 17, 2021, Petitioner filed an Affidavit in Support of Dr. Shoenfeld's Rebuttal Report—Exhibit 27 (ECF No. 90-1), and a Rebuttal Medical Expert Report and Amended Table of Exhibits—Exhibit 28 (ECF No. 90-2) (Shoenfeld Rebuttal Report or Shoenfeld Rebuttal Rep.). On February 16, 2022, the Special Master ordered the parties to file their briefs in preparation for adjudication. Feb. 16, 2022 Order at 3. On April 29, 2022, Petitioner filed her supplemental medical records and final exhibit list. *See* ECF Nos. 102-1 (Ex. 29), 102-2 (Ex. 30), 102-3 (Revised and Updated Table of Exhibits). On June 4, 2022, Petitioner filed her Final Brief in Support of Compensation. ECF No. 105 (Pet'r Pre-Hr'g Br.). On October 24, 2022, Respondent filed its Pre-Hearing Brief, ECF No. 113 (Resp't Pre-Hr'g Br.), and Briefing Order Statements of

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of the Order to Supplement—required for Petitioner's Supplemental Expert Report—and that he further ordered Petitioner to file a supplemental expert report by February 17, 2021. Order, dated Feb. 4, 2021 (ECF No. 67) (Feb. 4, 2021 Order) at 1–2.

its experts and its final Exhibit List. ECF Nos. 114-1 (Ex. E, Fadugba), 114-2 (Ex. F, Antiochos), 115 (Respondent's Pre-Hearing Exhibit List). On January 6, 2023, Petitioner filed her Optional Reply Brief. ECF No. 121-1 (Pet'r Reply).

On March 7, 2024, the Special Master denied Petitioner's Petition for Vaccine Compensation under the National Childhood Vaccine Injury Compensation Program. Decision Denying Compensation (ECF No. 123) (Decision)[11]; *Miller*, 2024 WL 1340598. On April 8, 2024, Petitioner filed a Motion for Review of the Decision pursuant to Rule 23 of Appendix B of the Rules of the United States Court of Federal Claims (Vaccine Rules). *See* Petitioner's Motion for Review (ECF No. 125) (Motion for Review, Motion, or Mot.). Petitioner also filed a Memorandum with her Motion detailing her objections to the Decision. *See* Obj. Mem.; Vaccine Rule 24.

III. Expert Opinions

A. Petitioner's Expert Report — Dr. Shoenfeld

Dr. Shoenfeld, Petitioner's expert, submitted a report concluding that the twelve days between vaccination and development of Petitioner's rash was "highly indicative of a causal relationship between the vaccine and . . . LCV." Shoenfeld Rep. at 6–7. He stated that onset of LCV following influenza vaccination has previously been reported, further claiming that the vaccine includes other molecules—meant to enhance an immune response—that can result in a damaging autoimmune response due to possible homology between vaccine proteins and human proteins (molecular mimicry and cross-reactivity). *Id.* at 8–9. In his description of the vaccine, Dr. Shoenfeld stated the current vaccine formulation "consists of live attenuated and inactivated

[11] The Special Master's March 7, 2024 Decision Denying Compensation was originally filed under seal and was later publicly reissued on March 29, 2024. ECF Nos. 123, 124.

influenza A (H1N1) . . . strain." *Id.* at 10. He further stated that the approved Influenza A 2009 (H1N1) seasonal influenza vaccines may contain adjuvants such as formaldehyde and Triton-X-100, which may cause "a dramatic increase in the antibody response." *Id.* at 10–12. He claimed the "unknown adjuvant property of the components of the current influenza vaccines" may be responsible for the increased reports of post-vaccination side effects, and specifically "associated with systemic disease, and the cutaneous [LCV]," though he acknowledged the mechanisms that lead from influenza to vasculitis "needs further research." *Id.* at 13.

Dr. Shoenfeld asserted four theoretical possibilities concerning how the influenza vaccine could cause LCV: (1) viral invasion of endothelial cells; (2) immune mediated damage of vessel walls due to deposition of immune complexes; (3) stimulation of lymphocyte proliferation, through different pathways, such as molecular mimicry or super-antigens; and (4) a combination of mechanisms. *Id.* at 14. He then noted the possibility of cross-reactivity because of the common peptides found in the vaccine as well as the human body: possible attack of numerous peptides associated with intracerebral hemorrhage; trapped protein leading to cerebral inflammation and vascular alterations; and possible stroke due to activation of peptide that may trigger brain damage via vascular disorders. *Id.* at 14–16.

Dr. Shoenfeld concluded it is more likely, in the absence of reasonable alternatives, that Petitioner's LCV, an autoimmune vascular disease, was caused by the vaccine. *Id.* at 22–23. He based this conclusion on the following: (1) Petitioner had no prior LCV symptoms or attributable medical history; (2) LCV developed within a medically reasonable time after the vaccine; (3) many similar cases have been reported; and (4) there is a plausible mechanism of molecular mimicry between viral peptides and vascular structures to explain LCV development. *Id.*

B. Respondent's Expert Report — Dr. Fadugba

In her expert report in support of Respondent, Dr. Olajumoke Fadugba first addressed Petitioner's medical disposition. She described Petitioner as having a history of type 2 pre-diabetes, obesity, and asthma. Fadugba Rep. at 2 (citing Ex. 4 at 6; Ex. 10 at 8). Regarding Petitioner's LCV diagnosis, Dr. Fadugba noted Dr. Schlessel's assessment that "there was no obvious etiology and no evidence of systemic vasculitis." *Id.* at 4 (citing Ex. 3 at 118) (emphasis omitted). Further, Petitioner's medical records document "weight loss in the setting of chronic illness." *Id.* at 5 (citing Ex. 3 at 521) (emphasis omitted). Dr. Fadugba emphasized (multiple times) that Petitioner declined cancer screening, including colonoscopy and mammogram, as well as evaluation for mycobacterium avium complex (MAC). *Id.* at 5–6 (citing Ex. 3 at 393, 469; Ex. 4 at 22, 23).

Dr. Fadugba explained that LCV is not a condition in and of itself, but rather a symptom of a separate condition, requiring evaluation for potential systemic manifestations, underlying causes, and disease associations. *Id.* at 6–7. She noted LCV is "often mediated by the *deposition of immune complexes (ICs) into vessels in the skin*." *Id.* at 7 (emphasis in original). She listed multiple causes of LCV: underlying connective tissue disease; infection; malignancy; and medications. *Id.* Finally, she noted that evaluation of LCV requires assessment for systemic involvement, and that a "[b]iopsy with direct immunofluorescence (DIF) is an essential part of LCV evaluation that persists [more than] 4 weeks, as it can help identify the cause." *Id.* at 8.[12]

Regarding adjuvants, Dr. Fadugba stated there was no evidence the Fluvirin vaccine contained Triton-X or formaldehyde. *Id.* at 9. She asserted that a number of publications upon

[12] She previously emphasized that, while the results of Petitioner's biopsy were "strongly suggestive of [LCV]," "[t]here was no immunofluorescence study performed to assess for presence of antibody, complement or immune complex deposits." Fadugba Rep. at 3 (emphasis omitted).

which Dr. Shoenfeld relied "relate to the *refuted phenomenon of Autoimmune/autoinflammatory syndrome induced by adjuvants (ASIA)*." *Id.* Dr. Fadugba also claimed the theory of viral invasion of endothelial cells is not valid because Fluvirin is an inactivated virus—*i.e.*, there is no live virus to invade endothelial cells. *Id.* at 10–11. Finally, Dr. Fadugba claimed the theory of immune mediated damage of the vessel walls due to deposition of immune complexes is not valid because there is no evidence of immune complex deposition in Petitioner's skin vessel walls. *Id.* at 11.

Dr. Fadugba also addressed Petitioner's "principle [sic] theory," molecular mimicry and cross-reactivity. *Id.* at 9. *First*, she claimed many of Dr. Shoenfeld's descriptions and examples relate to virus infection, rather than to the vaccine, which contains inactivated virus. *Id.* at 10. *Second*, she asserted that Dr. Shoenfeld's molecular mimicry theory is based on experimental data, much of which is based on animals, and further listed numerous potential cross-reactive antigens, "which do not reflect petitioner's actual vaccine antigen content." *Id.* *Third*, she contended that none of the required criteria have been established in the literature to link the influenza vaccine with vasculitis. *Id.* *Finally*, she explained that one would expect a much higher frequency of autoimmunity caused by molecular mimicry of the purported cross-reactive peptides, given the high frequency of influenza vaccination. *Id.*

Dr. Fadugba asserted there is a lack of epidemiological data to support a causal link between influenza vaccination and LCV *Id.* at 11. She noted 45 case reports regarding various types of vasculitis after influenza vaccine, and only eight specific reports of LCV. *Id.* (citing Ex. A-6 (ECF No. 79-7); Ex. A-7 (ECF No. 79-8)). Further, she pointed to a "more reliable" study of 31 patients with vasculitis, who suffered "no increase[d] rate of vasculitis flare" after receiving the 2007 annual influenza vaccine. *Id.* (citing Ex. A-8 (ECF No. 79-9)). She also cited several prospective studies demonstrating the influenza vaccine had no effect on "disease activity in

patients with various autoimmune disorders." *Id.* (citing Ex. A-9–13 (ECF Nos. 79-10–14)).

Regarding timing, Dr. Fadugba disagreed with Dr. Shoenfeld's 12-day onset duration, claiming case reports lacked evidence of causality, and accordingly that reliance on such reports is misplaced. *Id.* at 12. Finally, in response to Dr. Shoenfeld's assertion that no alternative explanation exists related to Petitioner's LCV, Dr. Fadugba cited the following as potentially indicative of alternative causes: (1) Petitioner's weight loss; (2) lack of malignancy screening; (3) lack of MAC screening; and (4) failure to explore explanations other than LCV for Petitioner's extensive thrombosis. *Id.* at 12–13.

C. Respondent's Expert Report — Dr. Antiochos

In his expert report submitted in support of Respondent, Dr. Brendan Antiochos briefly summarized Petitioner's medical history. In October 2016, Petitioner had been diagnosed with diabetes, asthma, and obesity, and she developed lesions compatible with LCV. Antiochos Rep. at 1–2 (citing Ex. 4 at 40). Dr. Antiochos stated that immunofluorescence testing was not performed with the biopsy, and Petitioner did not have a pulmonary evaluation for suspected infection. *Id.* at 2–3. He reiterated possible underlying conditions associated with LCV: rheumatic diseases, infections, malignancy, and medications, as well as primary vasculitis. *Id.* at 3. He further noted that Petitioner had anti-centromere antibodies, which are typically associated with three autoimmune diseases, including Sjogren's syndrome. *Id.* at 3–4 (citing Ex. 3 at 43; Ex. 4 at 9).

Dr. Antiochos asserted Dr. Shoenfeld's case reports (Ex. 23 (ECF No. 60-1)) were not evidence of causation because they did not scientifically establish a relationship between an exposure and outcome. *Id.* at 5. He cited a literature review that concluded, "Existing literature does not allow establishing a causative link between vaccination and vasculitides." *Id.* (quoting

Ex. C-9 (ECF No. 80-10) (Bonetto Article) at 2) (emphasis omitted).

Regarding adjuvants, Dr. Antiochos explained that Triton X-100 "is not present in this vaccine." *Id.* Regarding endothelial cell invasion, Dr. Antiochos asserted that Dr. Shoenfeld conflated the influenza virus with the vaccine, arguing it is inaccurate to assume infection would have the same impact on the host as vaccination. *Id.* at 6.

Regarding molecular mimicry, Dr. Antiochos noted the theory proposes a vaccine induces immunity against viral molecules that are similar to human proteins, "leading to the development of an anti-self immune response and subsequent tissue damage." *Id.* He explained that the asserted peptides are present in many organisms, concluding that "Dr. Shoenfeld simply demonstrates the simple fact that a relatively restricted set of 'ingredients' are utilized by all life forms on Earth." *Id.* at 7; *see id.* at 7–9. In summation, Dr. Antiochos concluded that Dr. Shoenfeld did not show any evidence suggesting the shared peptides caused Petitioner's autoimmunity, nor did Dr. Shoenfeld provide reliable evidence demonstrating the vaccine can induce vasculitis. *Id.* at 9. Dr. Antiochos therefore concluded there is no compelling evidence supporting a relationship between the influenza vaccine and LCV, and also noted that other potential causes of Petitioner's LCV were not investigated. *Id.* at 10.

D. Petitioner's Rebuttal Report — Dr. Shoenfeld

In his Rebuttal Report, Dr. Shoenfeld contended Respondent's experts ignored three facts: (1) Petitioner had no disease associated with LCV before the vaccine; (2) the time for onset of LCV was reasonable and a logical sequence following the vaccine; and (3) Petitioner did not and does not have Sjogren's Syndrome or malignancy. Shoenfeld Rebuttal Rep. at 1. He also reasserted that, in the absence of other reasonable alternative causes, the vaccine caused Petitioner's LCV, citing the following:

1) Prior to the vaccine she had no signs or symptoms of the vasculitis.

2) The vasculitis developed progressively within reasonable time after the vaccine was delivered.

3) There are many similar identical cases reported in the literature, to the case of Ms. Janie Miller.

4) There is a plausible mechanism of molecular mimicry between the viral peptides and vascular structures to explain the developments of the [LCV].

Id. at 1–2.

IV. The Special Master's Decision

On March 7, 2024, Special Master Christian J. Moran ruled Petitioner had not established entitlement to compensation. *Miller*, 2024 WL 1340598, at *1. Specifically, the Special Master ruled that Petitioner failed to demonstrate by preponderant evidence that "she reacted in a way that was consistent with" Dr. Shoenfeld's proposed theory. *Id.* In doing so, the Special Master noted the importance of refraining from imposing too high an evidentiary burden—*i.e.*, Petitioner must establish causation by preponderant evidence, not "medical certainty." *Id.* at *3–4.

In analyzing the action under prong one of the *Althen* test, the Special Master considered two types of evidence as sufficient to establish Petitioner's theory: medical articles regarding vaccinations causing vasculitis, and opinion testimony by Dr. Shoenfeld. *Id.* at *4. The "articles" included a "case report" and "leaflet" (Fluvirin Insert) that accompanied the vaccine. *Id.* The case report described a woman having two episodes of LCV one year apart, both 11 days after a she received the influenza vaccine. *Id.*; Ex. 13 (ECF No. 37-10) (Monjazeb Report) at 1. The Fluvirin Insert included "blood vessel inflammation" among "common side effects." *Miller*, 2024 WL 1340598, at *4 (internal citations omitted); Fluvirin Insert (ECF No. 37-9) at 2. The Special Master noted that neither Respondent nor its experts addressed these exhibits, and that they instead advanced an article that analyzed 75 studies regarding post-vaccination vasculitis, that concluded

"[e]xisting literature does not allow establishing a causative link between vaccination and vasculitides." *Miller*, 2024 WL 1340598, at *4 (citing Bonetto Article at 9).

As noted, the Special Master reviewed four proposed theories that Petitioner advanced in support of her position: (1) adjuvants; (2) "viral invasion of endothelial cells;" (3) molecular mimicry; and (4) immune complexes. *Id.* at *5–6.[13] The Special Master refuted three of the proposed theories in his *Althen* prong one analysis. *Id.* at *5. *First*, the Special Master disposed of Petitioner's adjuvants theory based on formaldehyde and Triton X-100, agreeing with Respondent that the influenza vaccine did not contain the stated adjuvants. *Id. Second*, the Special Master rejected Petitioner's viral invasion theory, agreeing with Respondent that the vaccine did not contain live virus that replicates. *Id. Third*, addressing Petitioner's molecular mimicry theory, the Special Master held that Dr. Shoenfeld had failed to explain "why the human peptide sequences contribute to the development of vasculitis." *See id.* (noting that Dr. Shoenfeld only asserted associated injuries that Petitioner did not claim).

However, regarding Petitioner's remaining immune complexes theory, the Special Master found that immune complexes (vessel wall damage due to deposition of immune complexes) could be the basis for a disease. *Id.* (citing *G.C. by Contino v. Sec'y of Health & Hum. Servs.*, No. 15-773V, 2019 WL 4941087 (Fed. Cl. Spec. Mstr. Sept. 5, 2019); *Fields v. Sec'y of Health & Hum. Servs.*, No. 02-311V, 2008 WL 2222141 (Fed. Cl. Spec. Mstr. May 14, 2008)); *see also* Shoenfeld

[13] Dr. Shoenfeld claims asserted adjuvants cause "a dramatic increase in the antibody response," which is associated with LCV as it is an autoimmune disorder. Shoenfeld Rep. at 11–12; *see also* Pet'r Pre-Hr'g Br. at 5. Dr. Shoenfeld also claims the viral invasion of endothelial cells "enhance[es] trans-endothelial migration of mononuclear cells and induction of transcripts for inflammatory cytokines and chemokines by the endothelial cells[.]" Shoenfeld Rep. at 14. Next, Dr. Shoenfeld claims molecular mimicry stimulates lymphocyte proliferation, and that immune cross-reactions between vaccine and human proteins may cause injury. *Id.* at 14–15. Finally, Dr. Shoenfeld claims the deposition of immune complexes may cause immune mediated damage of vessel walls. *Id.* at 14.

Rep. at 14. Specifically, the Special Master held that Respondent's expert, Dr. Fadugba, failed to challenge Petitioner's immune complexes theory, because he only maintained that Petitioner did not have immune complexes. *See Miller*, 2024 WL 1340598, at *5 (citing Fadugba Rep. at 11); *see also id.* (citing *Caves v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 119, 145 (2011), *aff'd without opinion*, 463 F. App'x 932 (Fed. Cir. 2012)) ("[W]hether a vaccine can cause a condition is analytically distinct from whether a vaccinee suffered from the condition."). As Petitioner's immune complexes theory was unrebutted, and Petitioner's proffered case report and leaflet constituted "some reliable evidence," the Special Master determined that Petitioner "can be assumed to have met her burden" at *Althen* prong one to establish that the flu vaccine could cause LCV. *Id.* at *6. Accordingly, Petitioner's immune complexes theory advanced to prong two of the *Althen* test.

At prong two of the *Althen* test, the Special Master held that Petitioner failed to show a logical sequence of cause and effect between the vaccine and immune complexes that cause LCV. *Id.* Specifically, the Special Master found that Dr. Shoenfeld did not rebut — nor did Petitioner argue against — Respondent's contention that Petitioner had provided no evidence that she had immune complexes that could cause the asserted vessel wall damage. *Id.* (citing Fadugba Rep. at 11); *see also Bourche v. Sec'y of Health & Hum. Servs.*, No. 15-232V, 2020 WL 571061 (Fed. Cl. Spec. Mstr. Jan. 7, 2020) (denying compensation because the evidence showed the vaccinee did not develop immune complexes).

The Special Master also discussed prong three of the *Althen* test, though he noted ruling on it was unnecessary, as Petitioner's theory did not meet the requirements of *Althen* prong two. *Miller*, 2024 WL 1340598, at *6. Both parties' experts generally agreed that two weeks is an appropriate length of time for development of LCV. *Id.* (citing Shoenfeld Rep. at 7; Fadugba Rep.

at 8). However, Dr. Fadugba additionally suggested Petitioner had an undiagnosed, pre-existing condition that could have caused the LCV. *Id.* (citing Shoenfeld Rep. at 4–5; Fadugba Rep. at 12; Resp't Pre-Hr'g Br. at 25). The Special Master did not resolve the issue, stating that even if Petitioner "had established that her vasculitis started 12 days after the vaccination, she would not necessarily be entitled to compensation." *Id.* at *7 (citing *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144 (Fed. Cir. 1992)).

V. Petitioner's Motion for Review

In her present Motion for Review, Petitioner echoes Dr. Shoenfeld's conclusion that "in the absence of many other reasonable, alternative causes, [] the flu vaccine is the cause of the [LCV]," based on the following: (1) Petitioner developed LCV shortly following the vaccine ("within the medically recognized time"); (2) Petitioner had no signs or symptoms of LCV or medical history of another condition to which the LCV could be attributed; (3) the LCV developed in a "historically consistent manner;" (4) "[t]here are many similar identical cases reported in the literature;" and (5) the "plausible mechanism of molecular mimicry" explains the development of LCV. Mot. at 3. Petitioner asserts Respondent's experts ignored strong circumstantial evidence, attempted to attribute the LCV to other causes, and failed to identify credible evidence that other circumstances could have caused Petitioner's LCV. *Id.* at 3–4. Accordingly, Petitioner makes the following objections:

> I. Petitioner objects to the Special Master's refusal to find that she satisfied prong III of the Althen case. The unchallenged evidence of temporal proximity between Petitioner being vaccinated and the onset of the vasculitis compelled such finding.
>
> II. In failing to find a sufficient temporal proximity under prong III of *Althen*, the Special Master neglected to consider the relevance of temporal proximity to the Petition'r's [sic] burden of proving causation under prong II of *Althen*.

III. In finding that Petitioner was not entitled to compensation, the Special Master misapplied the burden of proof by requiring the Petitioner to prove causation by direct evidence using scientific standards rather than legal probability.

Obj. Mem. at 1.

Further, Petitioner asserts the following: *First*, the Special Master allegedly failed to consider the Fluvirin Insert, with vasculitis as a potential adverse effect, as circumstantial evidence of causation; and further he allegedly erroneously decided that the only plausible theory causally connecting the vaccine to the injury was the immune complexes theory. *See id.* at 2–4. *Second*, Respondent purportedly failed to address significant medical literature provided by Petitioner. *Id.* at 4 & n.3. *Third*, Petitioner produced sufficient evidence of her pre- and post-vaccine medical history to support causation. *Id.* at 5. *Fourth*, Respondent allegedly failed to demonstrate that Petitioner suffered from the theorized underlying alternative causes, and that the Special Master erred in finding the evidence did not suggest the existence of immune complexes (despite acknowledging it could be a plausible theory). *See id.* at 5–8. *Fifth*, the Special Master's refusal to decide prong three purportedly precluded Petitioner from the benefit of relevant circumstantial evidence of causation. *See id.* at 8–10. Respondent responds to Petitioner's assertions as follows:

- The Special Master properly declined to rule on *Althen* prong three because Petitioner failed to satisfy prong two. Response to Petitioner's Motion for Review (ECF No. 127) (Resp't Resp.) at 10.
- The Special Master considered evidence related to temporal proximity and correctly concluded such evidence was insufficient to establish causation. *Id.* at 11.
- The Special Master applied the correct burden of proof—*i.e.*, preponderant evidence, rather than medical certainty. *Id.* at 13–14.
- The Special Master considered the Fluvirin Insert. *Id.* at 14.
- The Special Master correctly found Petitioner's alternative theories unpersuasive. *Id.* at 15.

- The Special Master did not ignore relevant circumstantial evidence—*e.g.*, medical literature, Petitioner's medical history, and proffered case law. *Id.* at 16–17.
- Respondent has no burden to prove an alternate cause of Petitioner's LCV. *Id.* at 18.

APPLICABLE LEGAL STANDARDS

The Vaccine Act created the National Vaccine Injury Compensation Program to compensate parties presumed or proven to be injured by certain vaccines. 42 U.S.C. § 300aa–10 *et seq.* The Program was designed to "lessen the number of lawsuits against manufacturers and provide[] relative certainty and generosity of compensation awards in order to satisfy petitioners in a fair, expeditious, and generous manner." *Cloer v. Sec'y of Health & Hum. Servs.*, 654 F.3d 1322, 1326 (Fed. Cir. 2011) (internal citations and quotation marks omitted) (alteration in original); *see also K.G. v. Sec'y of Health & Hum. Servs.*, 951 F.3d 1374, 1380 (Fed. Cir. 2020) (citing *Cloer*, 654 F.3d at 1325) ("The Vaccine Act is a pro-claimant regime meant to allow injured individuals a fair and fast path to compensation . . . .").

The Vaccine Act grants jurisdiction to the Office of Special Masters "over proceedings to determine if a petitioner . . . is entitled to compensation under the Program" for vaccine-related injuries or deaths and the amount of compensation owed. 42 U.S.C. § 300aa–12(a). Petitions alleging injuries are initially reviewed by a Special Master, who issues a decision on the petition. *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 228 (2011) (citing 42 U.S.C. §§ 300aa–11(a)(1), 12(d)(3)).

Section 300aa–12(e) of the Vaccine Act grants the United States Court of Federal Claims authority to review decisions of the Special Master upon a party's motion. 42 U.S.C. § 300aa–12(e)(1); *see* Vaccine Rule 23. In reviewing a Special Master's decision, this Court may

> set aside any findings of fact or conclusions of law . . . found to arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or . . . remand the petition to the special master for further action in accordance with the court's direction.

42 U.S.C. § 300aa-12(e)(2)(B)–(C); *accord* Vaccine Rule 27; *see Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 867 (Fed. Cir. 1992). Each standard of review referenced in the statute "applies to a different aspect of the judgment" and involves a different degree of deference given to the Special Master's determinations. *Munn*, 970 F.2d at 870 n.10. "Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the 'not in accordance with law' standard; and discretionary rulings under the abuse of discretion standard." *Id.*; *accord Markovich v. Sec'y of Health & Hum. Servs.*, 477 F.3d 1353, 1356 (Fed. Cir. 2007).

Petitioner may demonstrate eligibility for award in two ways: (1) by demonstrating that she received a vaccine listed on the Vaccine Injury Table, 42 U.S.C. § 300aa–14, and suffered an injury listed on that table within the statutorily prescribed time period; or (2) by demonstrating that the vaccine was the cause-in-fact of her condition where the injury is not on the Vaccine Injury Table. *Milik v. Sec'y of Health & Hum. Servs.*, 822 F.3d 1367, 1379 (Fed. Cir. 2016); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1319–20 (Fed. Cir. 2006) (citing *Munn*, 970 F.2d at 865). The parties agree here that Petitioner's claims concern alleged off-table injuries. *See* Pet'r Pre-Hr'g Br. at 4–5 (noting only the legal standard for non-table injuries); Resp't Pre-Hr'g Br. at 7 (same); *Miller*, 2024 WL 1340598, at *4 (same); *see also* Rule 4 Rep. at 4 ("The petition here does not allege a Table injury, and the records do not support that any injury listed on the Table occurred."). Regarding off-table injuries, Petitioner must prove by a preponderance of the evidence that her vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Petitioner must provide:

(1) a medical theory causally connecting the vaccination and the injury,

(2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury, and

(3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005); *see Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1354–55 (Fed. Cir. 2019) (quoting *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321–22 (Fed. Cir. 2010)). Petitioner must prove each *Althen* prong by a preponderance of the evidence. *Boatmon*, 941 F.3d at 1355.

At prong one, Petitioner must establish a "'reputable medical or scientific explanation' for [her] theory." *Boatmon*, 941 F.3d at 1359 (quoting *Moberly*, 592 F.3d at 1322). The theory must be "sound and reliable," though it "does not require medical or scientific certainty." *Id.* (quoting *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548–49 (Fed. Cir. 1994)). At prong two, Petitioner must demonstrate that "the vaccine caused [her] injury." *Capizzano*, 440 F.3d at 1326 (quoting 42 U.S.C. §§ 300aa–11(c)(1)–13(a)(1)). At prong three, Petitioner must demonstrate a temporal relationship between the vaccination and her injury. *See Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1358 (Fed. Cir. 2006); *see also id.* (citing *Capizzano*, 440 F.3d at 1326) ("Evidence demonstrating petitioner's injury occurred within a medically acceptable time frame bolsters a link between the injury alleged and the vaccination at issue under the 'but-for' prong of the causation analysis."). Evidence used to satisfy one prong may be used to satisfy the requirements of another *Althen* prong. *Capizzano*, 440 F.3d at 1326.

"Once a petitioner establishes a *prima facie* case, the government then bears the burden of establishing alternative causation by a preponderance of the evidence." *Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1335 (Fed. Cir. 2010) (citing *Walther v. Sec'y of Health & Hum. Sevrs.*, 485 F.3d 1146, 1151 (Fed. Cir. 2007)). However, if Petitioner fails to establish a *prima*

facie case, the burden does not shift to Respondent. *See Doe v. Sec'y of Health & Hum. Servs.*, 601 F.3d 1349, 1358 (Fed. Cir. 2010). Regardless of whether the burden shifts, the special master may consider evidence of alternative causation presented by the respondent in determining whether the petitioner has established a *prima facie* case, as the special master is to consider the record as a whole in determining causation where multiple possible sources of injury may exist. *Stone v. Sec'y of Health & Hum. Servs.*, 676 F.3d 1373, 1380 (Fed. Cir. 2010).

"[S]pecial masters have broad discretion to weigh evidence and make factual determinations." *Dougherty v. Sec'y of Health & Hum. Servs.*, 141 Fed. Cl. 223, 229 (2018). In adjudicating a Petition, the Court of Federal Claims does "not reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder." *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011); *see also Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 17-792V, at 12 (Fed. Cl. Oct. 27, 2022) (ECF No. 79) (internal citations omitted), *aff'd*, No. 2023-1321, 2024 WL 3064398 (Fed. Cir. June 20, 2024). Additionally, this Court should refrain from "'second guess[ing] the Special Master[']s fact-intensive conclusions' particularly in cases 'in which the medical evidence of causation is in dispute.'" *Cedillo*, 617 F.3d at 1338 (quoting *Hodges v. Sec'y of Health & Hum. Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993)). "[R]eversible error is extremely difficult to demonstrate if the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1381 (Fed. Cir. 2021) (quoting *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000)).

In weighing the evidence, the special master has discretion to determine the relative weight of the evidence, including medical records. *Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993); *see Hibbard v. Sec'y of Health & Hum. Servs.*, 698 F.3d 1355, 1368 (Fed. Cir. 2012). A special master is "not required to discuss every piece of evidence or testimony in [his or] her decision," as the special master is presumed to have considered the whole record. *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 728 (2009) (citing *Maza by Maza v. Sec'y of Health & Hum. Servs.*, 67 Fed. Cl. 36, 38 (2005)); *see Moriarty by Moriarty v. Sec'y of Health & Hum. Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) (internal citations omitted) ("We generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision. However, this presumption does not apply, as in this case, where a special master indicates otherwise."). The purpose of the Vaccine Act's standard of proof is "to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body," even if the alleged link is "hitherto unproven in medicine." *Althen*, 418 F.3d at 1280. Therefore, "close calls regarding causation are resolved in favor of injured claimants." *Id.* (citing *Knudsen*, 35 F.3d at 549).

DISCUSSION

As noted, Petitioner alleges the Special Master erred by: (1) refusing to find she satisfied the third *Althen* prong; (2) neglecting to consider temporal proximity in evaluating causation; and (3) misapplying the burden of proof of causation by requiring scientific certainty rather than preponderant evidence. Obj. Mem. at 1. In its response, Respondent refutes Petitioner's allegations and requests this Court deny Petitioner's Motion for Review. Resp't Resp. at 19. Specifically, Respondent contends that the Special Master (1) applied the correct burden of proof

at *Althen* prongs one and two, (2) considered relevant evidence and found it insufficient for causation; and (3) though not required to make a finding regarding *Althen* prong three, nevertheless considered temporal proximity and found it insufficient to support causation. *Id.* at 10–19.

The majority of Petitioner's assertions concern the Special Master's evaluation of causation at *Althen* prong two, as the Special Master held that Petitioner met her burden at prong one of providing a plausible medical theory linking the vaccine to the injury. *Miller*, 2024 WL 1340598, at *5. However, the Special Master only found one of Petitioner's four theories — immune complexes — plausible under *Althen* prong one and rejected three other theories advanced by Petitioner. *Id.* at *5–6. Petitioner waived her challenge to the Special Master's findings at *Althen* prong one, as she failed to state it as an objection or adequately raise it in her Motion for Review or Memorandum of Objections. *See generally* Mot.; *see* Obj. Mem. at 1; *see also* Vaccine Rule 24; *Civatte v. Sec'y of Health & Hum. Servs.*, 165 Fed. Cl. 520, 524 n.2 (citing Vaccine Rule 24; *Germaine v. Sec'y of Health & Hum. Servs.*, 155 Fed. Cl. 226, 228 n.3 (2021)). Though she did not properly object, Petitioner referenced the issue in her Memorandum of Objections, and Respondent briefed the issue in its Response. *See* Obj. Mem. at 3; Resp't Resp. at 15–16. Accordingly, this Court reviews the Special Master's finding that Petitioner's only valid theory to meet the standards of *Althen* prong one was her immune complexes theory.[14]

[14] At *Althen* prong one, the Court evaluates whether the Special Master's decision declining to accept a proffered theory was arbitrary or capricious by considering whether record evidence supports the existence of the mechanism required for the theory. *See K.A.*, 164 Fed. Cl. at 124 ("The court has reviewed petitioner's objection that the 'Chief Special Master failed to recognize that the posited medical theory of molecular mimicry went well beyond the mere identification of homologies between components of the Tdap vaccine and self-antigen such as human myelin protein, leading to GBS.' Petitioner did not offer reliable evidence to support the petitioner's theory that molecular mimicry between the Tdap antigens and self-structures associated with the initial attack on petitioner's nerves was the mechanism driving the autoimmune process. Therefore, based on the record . . . , this court finds that the . . . decision that petitioner has not established by a preponderance of the evidence that the Tdap vaccine likely caused the production of antibodies associated with autonomic damage or interference sufficient to cause GBS and that

Accordingly, this Court first evaluates whether the record supports the Special Master's rejection of Petitioner's three other proffered theories under *Althen* prong one. As described further below, because nothing in the record supports the existence of either the asserted adjuvants or live virus, and since Dr. Shoenfeld failed to specifically tie the noted peptides to LCV under his molecular mimicry theory, the Court holds that the Special Master's finding rejecting three of Petitioner's four theories at *Althen* prong one was well-founded and not arbitrary and capricious. Next, the Court will evaluate Petitioner's *Althen* prong two arguments, including whether the Special Master incorrectly required Petitioner to prove causation using scientific standards rather than preponderant evidence. As noted below, the Court holds that the Special Master considered all relevant evidence, including temporal proximity (typically considered at prong three), and properly determined, consistent with precedent, that nothing in the record supported the existence of the immune complexes necessary to demonstrate that Petitioner's theory actually occurred. Finally, the Court will consider Petitioner's contention that the Special Master erred in declining to rule on Petitioner's *Althen* prong three arguments. As described more fully below, the Court holds that the Special Master was not required to rule on Petitioner's *Althen* prong three arguments because Petitioner failed to meet her burden at prong two. The Court further notes that the Special Master was not required to consider temporal proximity in his causation analysis.

I. *Althen* Prong One

At *Althen* prong one, a petitioner must demonstrate the vaccine can cause Petitioner's alleged injury. *Pafford*, 451 F.3d at 1355–56. "[A] petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation

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those same antibodies did lead to pathogenic process was not arbitrary or capricious, or an abuse of discretion."); *see also infra* at Discussion Section I.

need only be 'legally probable, not medically or scientifically certain.'" *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1345 (Fed. Cir. 2010) (quoting *Knudsen*, 35 F.3d at 548–49). Each prong must be proved by a preponderance of evidence. *Boatmon*, 941 F.3d at 1355. In evaluating whether a special master failed to recognize a proposed theory, the Court reviews whether Petitioner offered reliable evidence on the record to support the theory. *See Broekelschen*, 618 F.3d at 1350–51 (affirming a finding of failure at prong one where the evidence relied upon (literature review) was weak and there was little evidence on the record regarding whether the influenza vaccine could cause the asserted injury).

Dr. Shoenfeld proposed four different avenues by which flu vaccination could allegedly result in LCV: (1) adjuvants; (2) "viral invasion of endothelial cells;" (3) molecular mimicry; and (4) immune complexes. *See Miller*, 2024 WL 1340598, at *5–6; Shoenfeld Rep. at 10–16. The Special Master found no record evidence supporting two of them (adjuvants and viral invasion). *Miller*, 2024 WL 1340598, at *5. Regarding molecular mimicry, the Special Master found Dr. Shoenfeld only provided explanation and literature regarding cross-reactions associated with injuries Petitioner did not allege. *Id.* at *5. The Special Master did, however, find that Petitioner's immune complexes theory was plausible, noting: (i) Petitioner's proffered literature (particularly, the Monjazeb Report) presented "an example of challenge-rechallenge, which can be evidence of causation," *id.* at *4 (citing *Stricker v. Sec'y of Health & Hum. Servs.*, No. 18-56V, 2024 WL 263189, at *25 (Fed. Cl. Spec. Mstr. Jan. 2, 2024)); and (ii) Respondent's expert, Dr. Fadugba, failed to challenge this theory, *id.* at *5 (citing Fadugba Rep. at 11; Resp't Pre-Hr'g Br. at 22).[15]

[15] The Special Master noted that instead of challenging the theory, "Dr. Fadugba maintained that Ms. Miller did not have immune complexes." *Miller*, 2024 WL 1340598, at *5 (internal citations omitted). Such an assertion, while pertinent to prong two, does not carry weight in the prong one analysis because "whether a vaccine can cause a condition is analytically distinct from whether a vaccinee suffered from the condition." *Id.* (citing *Caves*, 100 Fed. Cl. at 145).

A. The Special Master applied the correct burden of proof to reasonably find that Petitioner's immune complexes theory was the only plausible theory.

Petitioner asserts the Special Master erroneously found her asserted immune complexes theory was the only plausible medical theory of the four that she had advanced. Obj. Mem. at 3. Petitioner claims the Special Master required her to prove a medical theory of causation with scientific certainty, rather than by preponderant evidence. Mot. at 4. Contrary to Petitioner's assertion, the Special Master did not apply a heightened standard in analyzing the refuted theories. Instead, he specifically stated his application of the preponderance standard, and further properly noted that he should not impose too high a burden on Petitioner. *Miller*, 2024 WL 1340598, at *4; *see also Kalajdzic*, No. 17-792V (ECF No. 79), at 9 (finding the special master's conclusion sounded in preponderance where he specifically noted his conclusion "[did] not reflect a mistaken substitution of a standard of scientific certainty in place of . . . preponderance"). The correct burden at prong one is a demonstration of preponderant record evidence that the vaccine can cause the stated injury. *Kalajdzic*, 2024 WL 3064398, at *2. The Special Master found insufficient record evidence showing the Fluvirin vaccine could cause LCV via adjuvants, viral invasion, or molecular mimicry. As described further below, the Special Master's rejection of each of these three theories was reasonable.

1. Adjuvants

The Special Master determined the record did not support Petitioner's contention that the vaccine contained the adjuvants discussed by Dr. Shoenfeld. *Miller*, 2024 WL 1340598, at *5. Dr. Shoenfeld cited no literature regarding adjuvants in his claims about formaldehyde and Triton X-100. *See* Shoenfeld Rep. at 10–12.[16] His report lacks support concerning the presence of the

[16] The only nearby citation was to the article, Kirsty D. Ratanji *et al.*, *Immunogenicity of therapeutic proteins: Influence of aggregation*, J. OF IMMUNOTOXICOLOGY (2014), which makes only one reference to "adjuvants" and does not specifically state that this influenza vaccine

asserted adjuvants. *See id.* at 10 (noting, without cited support, that approved influenza vaccines "may contain" the noted adjuvants). Additionally, Respondent also rebutted Petitioner's contention, pointing to the reports of Dr. Fadugba and Dr. Antiochos, Respondent's experts, who each noted the Fluvirin Insert does not list those adjuvants. Resp't Pre-Hr'g Br. at 20. Petitioner only responded that the molecular mimicry theory is not dependent upon identifying a precise adjuvant. Pet'r Reply at 11. Moreover, Petitioner makes no reference to adjuvants in her Motion for Review. *See generally* Mot.; Obj. Mem.

A theory based on adjuvants is unpersuasive where the petitioner fails to establish that a vaccine contained such adjuvants. *See Valeen v. Sec'y of Health & Hum. Servs.*, No. 16-390V, 2021 WL 6137878, at *4–5 (Fed. Cl. Spec. Mstr. Nov. 30, 2021) (acknowledging there was competing testimony, but neither party cited any articles about the persistence or removal of the adjuvants). While not binding, the *Valeen* decision is persuasive. Here, as in *Valeen*, the Special Master found the record did not support that the vaccine contained the adjuvants. Petitioner neither provided record evidence that the asserted adjuvants were present in the vaccine, nor refuted Respondent's contention that they were not. *See* Shoenfeld Rep. at 10–12; Pet'r Reply at 11.

This Court also notes that there is persuasive record evidence that literature upon which Dr. Shoenfeld relies references the ASIA theory, which has been demonstrated to be unreliable. *See* Fadugba Rep. at 9 (citing Ex. A-4 (ECF No. 79-5) (Ameratunga Article) at 4 (internal citations omitted) ("[T]he association between vaccination and autoimmunity is likely to be spurious, most likely the result of random events or confounding rather than causality. From our review of the literature, vaccine adjuvant-induced ASIA does not appear to constitute a definable medical condition at this time.")). Further, in another action, Dr. Shoenfeld acknowledged that the ASIA

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contains them. ECF No. 65-9 (Ratanji Article) at 7, 8.

theory has not been accepted, and no study thus far has successfully related vaccines to autoimmune disease. *See Faup v. Sec'y of Health & Hum. Servs.*, No. 12-87V, 2019 WL 9313600, at *13 (Fed. Cl. Spec. Mstr. June 17, 2019).

The record clearly reflects that the Special Master "considered the relevant evidence of record," considered the expert's evaluation of the theory, and drew "plausible inferences and articulated a rational basis for the decision." *Kirby*, 997 F.3d at 1381. The Special Master therefore did not act arbitrarily or capriciously in finding that the record did not support Petitioner's adjuvant theory.

2. Viral Invasion of Endothelial Cells

The Special Master also rejected Petitioner's asserted viral invasion of endothelial cells theory at *Althen* prong one. Specifically, the Special Master found that the vaccine could not replicate to invade endothelial cells because it contained inactivated virus. *Miller*, 2024 WL 1340598, at *5. Dr. Shoenfeld made only passing reference to endothelial cells: stating possible invasion as a theory, and referencing one article. *See* Shoenfeld Rep. at 14, 30–31 (citing Andreas Fischer *et al.*, *Cerebral cavernous malformations: From CCM genes to endothelial cell homeostasis*, TRENDS IN MOLECULAR MEDICINE (2013)). Petitioner made no reference to this theory in her Pre-Hearing Brief, Reply Brief, or Motion for Review. *See generally* Pet'r Pre-Hr'g Br.; Pet'r Reply; Mot.; Obj. Mem. However, Respondent noted the impossibility of this theory because the Fluvirin vaccine is an inactivated virus. Resp. Pre-Hr'g Br. at 21 & n.5 (citing Fluvirin Insert; Fadugba Rep. at 11; Antiochos Rep. at 6).

The record supports that the vaccine contains inactivated virus. *See* Fluvirin Insert at 1. Moreover, Respondent's experts came to the same conclusion regarding the vaccine contents' inability to invade cells. Fadugba Rep. at 11; Antiochos Rep. at 6. Neither Petitioner nor her

expert rebutted this contention. *See generally* Pet'r Reply; Mot.; Obj. Mem. There is no evidence in the record to refute the Special Master's finding that Petitioner's viral invasion theory was unsupported. The Special Master therefore did not act arbitrarily or capriciously in finding that the record did not support Petitioner's viral invasion theory.

3. Molecular Mimicry

The Special Master found Dr. Shoenfeld failed to demonstrate how his asserted peptide sequences contributed to the development of vasculitis. *Miller*, 2024 WL 1340598, at *5. In support of Petitioner, Dr. Shoenfeld asserted that there have been cases where LCV was reported following influenza vaccination. Shoenfeld Rep. at 9. The molecular mimicry theory relies on cross-reactivity between vaccine and human proteins, and Dr. Shoenfeld noted the following injuries as associated with the listed cross-reactions: intracerebral brain hemorrhage, cerebral inflammation and vascular alterations, and precursor to stroke. *Id.* at 14–22. Respondent relied on proffered medical literature to assert Dr. Shoenfeld's theory did not meet the four criteria established for molecular mimicry, and argued shared peptides are found across many organisms. Resp't Pre-Hr'g Br. at 16–17 (citing Ex. A-5 (ECF No. 79-6) (Peterson Article) at 1; Ex. C-10 (ECF No. 80-11) (Roudier Article)).

Petitioner's molecular mimicry theory relies on Dr. Shoenfeld's recitation of certain homologous peptides (common to the vaccine and the human body), asserting the immune cross-reactions might attack certain proteins and cause injury. *See* Shoenfeld Rep. at 14–22. The Federal Circuit recently affirmed a finding where a special master reasonably rejected a molecular mimicry theory in which petitioner offered no more than identification of homologous peptides. *See K.A. v. Sec'y of Health & Hum. Servs.*, 164 Fed. Cl. 98, 123–24 (2022), *aff'd without opinion*, 2024 WL 2012526 (Fed. Cir. May 7, 2024) (quoting *Pierson v. Sec'y of Health & Hum. Servs.*, No. 17-

1136V, 2022 WL 322836, at *25 (Fed. Cl. Spec. Mstr. Jan. 19, 2022) (quoting *Brayboy v. Sec'y of Health & Hum. Servs.*, No. 15-183V, 2021 WL 4453146, at *19 (Fed. Cl. Spec. Mstr. Aug. 30, 2011))) ("[A] 'petitioner must offer more than superficial invocation of molecular mimicry as the causal mechanism,' and '[i]t also cannot be enough that a medical expert can simply identify homologous peptides from a generic BLAST search that are not, in any way linked to the biological process that is dysfunctional or has suffered injury."). Indeed, "petitioner must prove a medical theory by a preponderance of the evidence that a vaccination can cause a particular injury." *Kalajdzic*, 2024 WL 3064398, at *2 (citing *Althen*, 418 F.3d at 1278; *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1351 (Fed. Cir. 2008); *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013)) (affirming a finding of failure at prong one where evidence supported a link between narcolepsy and a different flu vaccine than the specific vaccine at issue).

Similar to *K.A.*, the Special Master found Dr. Shoenfeld failed to demonstrate how the asserted peptide sequences contributed to the development of vasculitis, noting Petitioner did not suffer from the stated associated injuries—*e.g.*, cerebral hemorrhage. *Miller*, 2024 WL 1340598, at *5. Dr. Shoenfeld's cited references only list injuries that Petitioner did not claim; LCV was not specifically addressed in the referenced literature. *See* Shoenfeld Rep. at 23–31 (references). As record evidence did not establish a link between the asserted cross-reactions and Petitioner's injury, the Court cannot find that the Special Master acted arbitrarily or capriciously in finding that the record did not support Petitioner's molecular mimicry theory. *See Kalajdzic*, 2024 WL 3064398, at *2; *see also Trollinger v. Sec'y of Health & Hum. Servs.*, 167 Fed. Cl. 127, 141–42 (2023).

B. The Special Master considered Petitioner's proffered medical literature.

The Special Master did not fail to consider Petitioner's proffered medical literature at prong

one. As noted, the Special Master did in fact consider the Fluvirin Insert and Monjazeb Report. While the Special Master noted that Respondent's proffered Bonetto Article merited consideration, he accepted Petitioner's proffered evidence as sufficient to evaluate Petitioner's proffered theories and causation. *Miller*, 2024 WL 1340598, at *4–6. Petitioner also asserts, however, that "Respondent elected not to address any of our referenced medical literature or relevant vaccine program cases that recognized LCV as a suspected reaction to flu vaccination." Obj. Mem. at 4; *see id.* at 4 n.3 ("See Petitioner's Exhibits 25-1 to 25-9 at Doc.65[.]").

First, Exhibit 25 (ECF No. 65) was replaced by Dr. Shoenfeld's final expert report. *See supra* Background Section II. *Second*, the Special Master cited each of the documents referenced by Petitioner in his final report (ECF No. 72).[17] The Special Master is presumed to have considered all proffered evidence, unless he indicates otherwise. *See Moriarty*, 844 F.3d at 1328; *Snyder*, 88 Fed. Cl. at 728. He did not so indicate. Respondent noted that Dr. Shoenfeld's opinions were reliant on case studies, which are less persuasive and reliable than epidemiological studies. Resp't Pre-Hr'g Br. at 18 (citing *Grant*, 956 F.2d at 1144; *Porter*, 663 F.3d at 1253–54; Fadugba Rep. at 11; Antiochos Rep. at 5). Despite Respondent's contention, the Special Master accepted a case study proffered by Petitioner (the Monjazeb Report). Indeed, there is no support for a finding that the Special Master failed to consider Petitioner's proffered medical literature.

II. *Althen* Prong Two

Petitioner claims that the Special Master "misapplied the burden of proof by requiring the petitioner to prove causation by direct evidence using scientific standards rather than legal

[17] While Exhibit 25 was replaced by Exhibit 26, the Shoenfeld Report (ECF No. 72-1), which did not attach any separate literature, the Shoenfeld Report cites each of the nine Exhibit 25 literature references (ECF Nos. 65-2–10). *See* Shoenfeld Rep. at 25–26 (listing references 14–22, which correspond with ECF Nos. 65-2–10).

probability." Obj. Mem. at 1. *First*, Petitioner asserts that "[t]he entire context of the Respondent's experts' critique is alleging that the Petitioner has failed to satisfy scientific standards of proof." Mot. at 4. *Second*, Petitioner contends the Special Master primarily focused on scientific evidence regarding possible causes of LCV and failed to review all circumstantial evidence. Obj. Mem. at 5–6. *Third*, Petitioner asserts that medical certainty is not required to prove causation. *Id.* at 10–11. Petitioner generally focuses on the adequacy of the circumstantial evidence provided to the Special Master, contending that the Special Master should have come to a different conclusion. *See generally id.* In response, Respondent contends the Special Master applied the correct burden of proof by articulating that he must distinguish between preponderant evidence and medical certainty so as to not impose too high an evidentiary burden. Resp't Resp. at 14. Respondent further asserts Petitioner failed to identify an instance where the Special Master required "direct" medical evidence.[18] *Id.*

The Special Master found Petitioner failed to demonstrate she had immune complexes—*i.e.*, that her theory actually occurred. *See Miller*, 2024 WL 1340598, at *6 (citing *Bourche*, 2020 WL 571061 (denying compensation because the vaccinee did not develop immune complexes)); *see also Baldwin v. Sec'y of Health & Hum. Servs.*, 151 Fed. Cl. 431, 447 (2020) (citing *Broekelschen*, 618 F.3d at 1339) (requiring petitioner to demonstrate "by a preponderance of the evidence that one of her expert's theories actually occurred").

[18] Respondent asserts Petitioner did not identify an instance where she was "required to satisfy the first *Althen* prong with 'direct' evidence." Resp't Resp. at 14. However, this assertion was in response to Petitioner's "third assignment of error," and Respondent specifically references causation. *Id.* at 13–14. Petitioner's third alleged error was that "the special master misapplied the burden of proof by requiring the petitioner to prove causation by direct evidence." Obj. Mem. at 1. This Court therefore construes Respondent's claim as related to causation at prong two.

A. The Special Master applied the appropriate burden of proof.

1. The Special Master's decision is consistent with precedent requiring a demonstration that the vaccine caused Petitioner's injury.

At prong two, Petitioner must prove actual causation by a preponderance of the evidence. *Boatmon*, 941 F.3d at 1355. The Federal Circuit has "consistently rejected theories that the vaccine only 'likely caused' the injury and [has] reiterated that a 'plausible' or 'possible' causal theory does not satisfy the standard." *Id.* at 1359–60 (quoting *Moberly*, 592 F.3d at 1322). The Special Master must also consider the opinions of treating physicians. *See Capizzano*, 440 F.3d at 1326 (finding error in failing to consider physician opinions concluding the vaccine caused injury, even if they relied in part on temporal proximity).

As noted, Petitioner contends that the Special Master imposed a heightened burden of proof that is purportedly inconsistent with previous grants of entitlement based on similar evidence and expert analysis. Petitioner references *G.C. by Contino v. Secretary of Health & Human Services*, No. 15-773V, 2019 WL 4941087 (Fed. Cl. Spec. Mstr. Sept. 5, 2019), to assert a special master has previously granted entitlement for injury caused by urticaria vasculitis based on similar expert analysis that apparently relied on same or similar articles regarding autoimmune response. Pet'r Pre-Hr'g Br. at 14–15; *see also* ECF No. 105-1 (*Contino*, No. 15-773V, Ruling on Entitlement). Petitioner's reliance on *Contino* is misplaced, as the facts in *Contino* are distinguishable from the present action. In *Contino*, the petitioner had a skin biopsy with DIF revealing granular deposition of particles associated with vasculitis. *Contino*, 2019 WL 4941087, at *5, *11. An expert therefore concluded, "[T]he IgM anti-IgE receptor antibodies produced the rash and also produced the antigen-antibody complexes, that embedded themselves into the vessels, fixing complement, which is what led to the vasculitis." *Id.* at *16. In contrast here, while Petitioner had a skin biopsy, there is no record of DIF testing to confirm the existence of immune complexes. *See* Fadugba

Rep. at 3, 8, 11; Antiochos Rep. at 2–3; *see also* Resp't Pre-Hr'g Br. at 2–3 (citing Ex. 4 at 40). Petitioner failed to rebut these assertions or provide evidence of testing. *See generally* Pet'r Reply.

The Special Master relied on *Bourche v. Secretary of Health & Human Services* in support of his finding that Petitioner failed to prove causation by failing to demonstrate the presence of immune complexes. *Miller*, 2024 WL 1340598, at *6. Petitioner asserts *Bourche* is distinguishable from her case, and instead proposes a comparison to *Moriarty v. Secretary of Health & Human Services*, 130 Fed. Cl. 573, 577–78 (2017). *See* Obj. Mem. at 9–10 & n.6. *Bourche* is distinguishable from the facts here, but not in a manner helpful to Petitioner. There, similar to *Contino*, the petitioner had a skin biopsy subject to DIF, the results of which enabled the special master to conclude that record evidence did not demonstrate that petitioner formed immune complexes. *See Bourche*, 2020 WL 571061, at *2, *19; *see also id.* at *20 ("The lack of IgG in [petitioner's] skin biopsy undermines the theory that an adverse reaction to the hepatitis B vaccine caused his vasculitis.").

Petitioner instead points to *Moriarty* to argue the Court of Federal Claims has granted compensation based on the immune complexes theory. This comparison is also unhelpful to Petitioner. The *Moriarty* court remanded the action to the special master for failure to rely on testimony and evidence offered by petitioner's expert demonstrating causation, and for relying too heavily on the fact that no tests were conducted to provide affirmative evidence of antibodies. *Moriarty*, 130 Fed. Cl. at 577–78. The court further faulted the special master for dismissing the views of multiple treating physicians who noted petitioner's issues were attributable to the vaccine. *Id.* In the instant case, while the Special Master similarly relied on the lack of testing to provide affirmative evidence of antibodies, the record lacks evidence of Petitioner's treating physicians attributing her LCV to the vaccine. *See infra* Discussion Section II(A)(2)(b).

Finally, the Special Master properly relied on *Fields v. Secretary of Health & Human Services* to state that immune complexes could be the basis for a disease. *Miller*, 2024 WL 1340598, at *5 (citing *Fields*, 2008 WL 2222141). In *Fields*, the special master found the petitioner was entitled to compensation and in doing so, rejected respondent's assertion that petitioner could not prevail where she was not tested for the presence of immune complexes. *See* 2008 WL 2222141, at *12 (quoting *Knudsen*, 35 F.3d at 549) (internal citations omitted) ("'[T]o require . . . proof of specific biological mechanisms would be inconsistent with the purpose and nature of the vaccine compensation program.' Therefore, respondent's argument is rejected as placing too high a burden on [petitioner]. In short, [petitioner's] history of symptoms is consistent with a slowly developing form of Wegener's granulomatosis. Thus, she has established a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'"). While the decision in *Fields* relied upon significant symptoms consistent with the diagnosis, the special master also heavily relied on personal and expert testimony due to a dearth of treatment and testing from the time of onset. *Id.* at *1–4. Here, however, there were significant contemporaneous treatment, testing, and records maintained, yet as noted, there were no contemporaneous opinions linking Petitioner's LCV to the vaccine. *See generally* Exes. 3, 4, 29, 30; *see also* Ex. 3 at 118 (noting "there is no obvious etiology" of Petitioner's LCV).

At prong two, petitioners are required to demonstrate that the vaccination caused the condition of the vaccinee in question. *Pafford*, 451 F.3d at 1355–56; *Trollinger*, 167 Fed. Cl. at 133 ("Althen prong[] two . . . require[s] . . . showing[] of 'a logical sequence of cause and effect showing that the vaccination was the reason for the injury.'"). Testing (DIF) demonstrating immune complexes has been deemed sufficient to demonstrate causation under the immune complexes theory. *See Contino*, 2019 WL 4941087, at *5, *11. However, while a lack of testing

may not be dispositive, this Court has denied compensation where petitioners also failed to demonstrate any contemporaneous medical opinion in the record that the vaccine caused the injury. *See Baldwin*, 151 Fed. Cl. at 447 (internal citations omitted) ("None of the treating physicians who contemporaneously examined Petitioner drew a connection from the cardiac event to the vaccine. Indeed, the Special Master noted that even though Dr. Cordas was aware that Petitioner was pursuing a vaccine-injury claim, he nevertheless could not 'directly link' Petitioner's flu vaccination to her . . . cardiac arrest . . . ."); *see also Stapleford v. Sec'y of Health & Hum. Servs.*, No. 03–234V, 2009 WL 1456441, at *17 (Fed. Cl. May 1, 2009) (internal citations omitted) (noting that treating physicians stated, "I am uncertain as to what precipitated the seizures," "'no definitive diagnosis' concerning the cause of the seizures," and "[petitioner's] seizure disorder was 'of unknown etiology'").

Here, there is no record of testing to establish the presence of immune complexes. *See Baldwin*, 151 Fed. Cl. at 447 ("This argument [that "these tests are not routinely administered"] is unavailing because, as noted, Petitioner did receive medical tests which could have confirmed Petitioner's theory."). Further, Petitioner failed to demonstrate any contemporaneous medical opinions linking the influenza vaccine to her LCV. *Compare* Ex. 3 at 118 ("[T]here is no obvious etiology of [Petitioner's LCV]."), *with Stapleford*, 2009 WL 1456441, at *17 ("[Petitioner's] seizure disorder was 'of unknown etiology."). The Special Master's decision denying compensation due to Petitioner's lack of causation evidence is therefore appropriate and consistent with precedent. *See Baldwin*, 151 Fed. Cl. at 447 (citing *Moberly*, 592 F.3d at 1323–24). Additionally, it is evident that the Special Master did not apply a heightened standard of proof. Rather, he reasonably concluded, based on record evidence, that Petitioner failed to demonstrate causation by preponderant evidence, as the determination was based on his consideration of

Petitioner's proffered medical literature and records, as well as Respondent's asserted underlying conditions that could have caused the injury. *Miller*, 2024 WL 1340598, at *4–6. The Court addresses each of Petitioner's asserted associated errors below.

2. The Special Master did not err in considering medical literature, medical records, or proffered alternative causes.

a. The Special Master considered Petitioner's proffered medical literature.

As noted, Petitioner contends that the Special Master failed to consider her proffered medical literature in making his determination. Obj. Mem. at 2–4 & n.3. Petitioner argues the Fluvirin Insert, listing vasculitis as a potential adverse effect and accepted by the Special Master as reliable evidence, is relevant circumstantial evidence of causation under prong two, the oversight of which constitutes reversible error. *Id.* at 2–3. Respondent asserts the Special Master considered such evidence but also notes that "package inserts are not sufficient by themselves to prove causation." Resp't Resp. at 14 (citing *Sullivan v. Sec'y of Health & Hum. Servs.*, No. 10-398V, 2015 WL 1404957, at *20 (Fed. Cl. Spec. Mstr. Feb. 13, 2015) (citing *Werderitsh v. Sec'y of Health & Hum. Servs.*, No. 99-319V, 2005 WL 3320041, at *8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005) (quoting 21 C.F.R. § 600.80(l)))).[19]

Petitioner further argues she submitted sufficient medical literature linking the influenza vaccine to LCV, as well as a case granting entitlement based on allegedly similar theory and circumstances—*G.C. by Contino v. Sec'y of Health & Hum. Servs.*, No. 15-773V, 2019 WL 4941087 (Fed. Cl. Spec. Mstr. Sept. 5, 2019). Obj. Mem. at 4. Respondent asserts it is assumed

[19] Though *Sullivan* cites to subsection (l) of section 600.80, the quoted language, slightly modified, now resides in subsection (n): "A report of information submitted by an applicant under this section (and any release by DFA of that report or information) does not necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the biological product caused or contributed to an adverse effect." 21 C.F.R. § 600.80(n).

that the Special Master considered all presented evidence, even if he did not discuss it, and that the Special Master did not err in not considering *Contino* because he is not bound by that decision. Resp't Resp. at 17–18 (citing *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App'x 952, 959 (Fed. Cir. 2011); *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998)).

First, even if *Contino* were binding, which it is not, this Court has already noted important distinctions here from Petitioner's claim. *See supra* Discussion Section II(A)(1). Moreover, the Special Master is presumed to have considered all proffered evidence, even if he does not specifically discuss each piece of evidence submitted, and furthermore, there is no indication that he did not consider the proffered medical literature. *See Moriarty*, 844 F.3d at 1328; *Snyder*, 88 Fed. Cl. at 728; *see also supra* Discussion Section I(B).

The Special Master expressly noted Petitioner's proffered literature and Fluvirin Insert to find Petitioner met her burden at prong one—*i.e.*, that the vaccine *could* cause LCV. *Miller*, 2024 WL 1340598, at *6. The inquiry at prong two, however, is whether the "*particular* vaccination *did* cause the *particular* condition of the vaccinee in question." *See Stapleford*, 2009 WL 1456441, at *18 (citing *Pafford*, 451 F.3d at 1355–56) (emphasis in original). Specifically, the Special Master relied on proffered medical literature to find that the influenza vaccine *could* cause LCV, but found that Petitioner did not demonstrate that the vaccine *did* cause her LCV via immune complexes. *Miller*, 2024 WL 1340598, at *6. The reasonableness of that finding, based on record evidence, is not altered by the cited literature. *See* Ex. 3 at 118 (noting no known etiology of Petitioner's LCV); Obj. Mem. at 7 ("Since [Petitioner] was never tested for the existence of immune complexes, [Dr. Fadugba] doesn't know (and neither does the Special Master) whether they were ever present.").

b. The Special Master considered Petitioner's medical records and the opinions of Petitioner's treating physicians.

Petitioner further contends that the Special Master failed to consider her medical records and the opinions of her treating physicians. Obj. Mem. at 5. In support of her contention, Petitioner asserts that she produced several written testimonials describing her medical history and habits in her own words. *Id.* Respondent counters that the Special Master devoted several pages of his decision to Petitioner's pre- and post-vaccination records. Resp't Resp. at 17 (citing *Miller*, 2024 WL 1340598, at *2–4). Respondent further asserts "no treating provider opined that petitioner's flu vaccination was causally related to her condition." *Id.* at 11. Though the Special Master described Petitioner's full medical history, he did not address whether LCV caused Petitioner's DVT/PE as it was unnecessary to do so.[20] *See generally Miller*, 2024 WL 1340598, at *6. Instead, in making his determination, the Special Master properly considered the possibility that immune complexes could theoretically cause LCV but found that Petitioner failed to provide evidence that she, in fact, had immune complexes. *Id.* As Petitioner is required at prong two to demonstrate that the vaccine was the but-for cause of the injury, she was required to provide record evidence demonstrating that the vaccine was more than just a possible cause of her LCV—all of which the Special Master acknowledged. *See id.*; *Boatmon*, 941 F.3d at 1359–60.

Petitioner's medical records are devoid of conclusions regarding the complications from the vaccine or causation generally. *See generally* Exes. 3, 4, 29, 30. Indeed, Petitioner's treating

[20] Petitioner improperly focuses on DVT/PE, which her medical records demonstrate resulted from her LCV. *See* Obj. Mem. at 12 ("[T]he Court is urged to remand the case for a determination of whether the Petitioner's thrombotic events of widespread PE and DVT . . . were likely the consequence of the LCV . . . ."); Ex. 4 at 41 (noting that Petitioner's DVT/PE "occurred in the setting of an acute inflammatory condition secondary to [LCV] and elevated BMI"). The proper inquiry, however, is whether the vaccine caused Petitioner's LCV, otherwise the vaccine could not have been the cause of the DVT/PE.

physicians in November of 2016, upon first examination of her LCV rash, did not mention the vaccine as a likely cause, much less an actual cause of Petitioner's injury. *See generally* Exes. 3, 4. Later, in December 2016, a different physician, Dr. Schlessel, stated there was "no obvious etiology [of Petitioner's "[c]utaneous leukocytoclastic vasculitis"]." Ex. 3 at 118; Ex. 4 at 13; *see Stapleford*, 2009 WL 1456441, at *17. A treating physician did acknowledge Petitioner's diagnosis of DVT/PE as associated with LCV. Ex. 4 at 41 ("This occurred in the setting of an acute inflammatory condition secondary to leukocytoclastic vasculitis and elevated BMI (34)."). Such a conclusion, however, does not link the vaccine to Petitioner's vasculitis. *See supra* note 20. The Special Master therefore reasonably found that record evidence did not support the conclusion that the Fluvirin vaccine caused Petitioner's LCV. *See Moberly*, 592 F.3d at 1323–24 (finding no error in rejecting causation where no treating physician drew a causal connection between the vaccine and petitioner's injury); *see also Baldwin*, 151 Fed. Cl. at 447.

c. The Special Master did not err in considering proffered alternative underlying conditions.

Petitioner asserts that, though Respondent suggested the presence of malignancy, diabetes, or Sjogrens Syndrome as alternative causation for her injuries, Respondent failed to demonstrate Petitioner actually suffered any of these. Obj. Mem. at 5–6.[21] Petitioner further asserts that, though the Special Master acknowledged the immune complexes theory, he erred in finding that "the evidence does not support a finding that Ms. Miller had immune complexes." *Id.* at 7 (quoting *Miller*, 2024 WL 1340598, at *6). Petitioner claims that when considered with the totality of the circumstances, and in the light most favorable to her, Petitioner likely suffered from the accepted

[21] Petitioner specifically argues she did not have diabetes—only "pre-diabetes" "controlled with diet alone," Obj. Mem. at 5 n.4, and that she was never prescribed diabetic medication until treated with prednisone. *Id.* at 5.

medical theory sufficient for causation under prong two. *Id.* at 7–8 (citing *Tenneson v. Sec'y of Health & Hum. Servs.*, No. 16-1664V, 2018 WL 3083140, at *6 (Fed. Cl. Spec. Mstr. Mar. 30, 2018), *review denied*, 142 Fed. Cl. 329 (2019)). Respondent asserts the burden only shifts to Respondent after Petitioner establishes a *prima facie* case. Resp't Resp. at 18 (citing *de Bazan*, 539 F.3d at 1352 (citing 42 U.S.C. § 300aa-13(a)(1)(B)); *Walther*, 485 F.3d at 1150).

It is well-established that the burden does not shift to Respondent to prove alternative causation if Petitioner does not establish her *prima facie* case. *Snyder*, 88 Fed. Cl. at 742 (citing *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993)) ("However, if a petitioner fails to establish a *prima facie* case, the burden does not shift."); *see Cedillo*, 617 F.3d at 1335. Accordingly, as Petitioner failed at prong two and did not meet her initial burden to establish a *prima facie* case, the burden did not shift to Respondent to prove alternative causes by preponderant evidence. *See Miller*, 2024 WL 1340598, at *6; *see also Snyder*, 88 Fed. Cl. at 742. Regardless of whether the burden shifted to Respondent, however, it is well-established that the Special Master was permitted to consider evidence of alternative causes in evaluating Petitioner's *prima facie* case.[22] *See Stone*, 676 F.3d at 1380; *see also K.A.*, 164 Fed. Cl. at 116, 118 (citing *Stone*, 676 F.3d at 1380); *see also Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (finding the special master's acceptance of respondent's asserted likely cause reasonable because it was supported by petitioner's medical records).

Here, the Special Master considered the underlying, alternative causes asserted by

[22] For example, the Special Master acknowledged that diabetes mellitus was an issue addressed by one of Petitioner's providers. *Miller*, 2024 WL 1340598, at *1 (citing Ex. 4 at 1); *see also* Fadugba Rep. at 2 (citing Ex. 4 at 6; Ex. 10 at 8); Antiochos Rep. at 2; Resp't Pre-Hr'g Br. at 1 (citing Ex. 4 at 6; Ex. 10 at 8). Respondent's proffered literature demonstrates that diabetes is an underlying condition associated with LCV. *See* Ex. A-3 (ECF No. 79-4) (Carlson Article) at 12 (listing diabetes mellitus as a chronic disease factor associated with vasculitis).

Respondent's experts only in evaluating temporal proximity. *See Miller*, 2024 WL 1340598, at *6 (finding two weeks an appropriate timeframe for onset of LCV, but noting the asserted underlying conditions as affecting when onset allegedly occurred). The Special Master noted the alternative causes as possibly affecting temporal proximity, but he did not find that Petitioner failed to prove causation because of Respondent's proffered alternative causes. *See Miller*, 2024 WL 1340598, at *6. The Special Master therefore did not act arbitrarily or capriciously in acknowledging the likely existence of an underlying condition.

* * *

The Special Master applied the correct burden of proof in requiring Petitioner to prove by record evidence that the vaccine caused her injury—*i.e.*, that she actually suffered the immune complexes contemplated by her valid medical theory, or that treating physicians contemplated the vaccine as a cause. The record demonstrates that no testing was conducted to confirm the presence of immune complexes, and that no treating physician noted the vaccine as a possible cause of Petitioner's LCV. The Special Master therefore did not act contrary to law in holding that Petitioner failed to meet her burden to prove causation at *Althen* prong two.

B. The Special Master did not err in finding that possible temporal proximity was insufficient to establish causation.

Petitioner asserts that a strong temporal relationship and the entire record support causation, therefore making the case a "close call" that should be resolved in her favor. *See* Obj. Mem. at 9–12; *id.* at 11 (quoting *Tenneson*, 2018 WL 3083140, at *6). Petitioner points to the Special Master's purported decision to forgo addressing *Althen* prong three, claiming that it affected his ruling on prong two and demonstrated that the Special Master did not consider the entire record. *Id.* at 8–12 (citing *Moriarty*, 844 F.3d at 1327). Respondent counters that the Special Master did consider temporal proximity in his decision and correctly found it insufficient to

establish causation. Resp't Resp. at 11. The Special Master acknowledged agreement on the appropriate onset timeframe but noted disagreement among the experts regarding the onset of Petitioner's LCV. *See id.* at 12; *Miller*, 2024 WL 1340598, at *6. Respondent therefore claims the Special Master correctly found resolution was not required because temporal proximity alone was insufficient for causation. Resp't Resp. at 12 (citing *Miller*, 2024 WL 1340598, at *7 (citing *Grant*, 956 F.2d at 1148)).

Though, as discussed below, the Special Master discussed temporal proximity at prong three, as noted, he ultimately declined to rule on Petitioner's *Althen* prong three arguments. *Miller*, 2024 WL 1340598, at *6. The Special Master instead found that Petitioner's assertions of temporal proximity would have been insufficient to support causation. *Id.* at *7. He acknowledged that both Petitioner's and Respondent's experts (Dr. Shoenfeld and Dr. Fadugba) generally agreed two weeks would be an appropriate time to develop LCV following vaccination. *Id.* The Special Master also, however, considered Respondent's experts' suggestion that undiagnosed pre-existing conditions may have caused the development of Petitioner's LCV, though he aptly stated that resolving the issue was not required. *Id.* at *6–7 (internal citations omitted) ("Dr. Fadugba suggests that Ms. Miller had an undiagnosed pre-existing problem, such as some type of cancer, that could have caused her vasculitis."); *see also supra* Discussion Section II(A)(2)(c).

The Special Master was entitled to consider Respondent's assertions regarding Petitioner's pre-existing conditions, though, as noted, Respondent did not have a burden to prove them. *See Stone*, 676 F.3d at 1380 (citing *Doe*, 601 F.3d at 1356–58) ([T]he special master is entitled to consider the record as a whole in determining causation, especially in a case involving multiple potential causes acting in concert, and no evidence should be embargoed from the special master's consideration simply because it is also relevant to another inquiry under the statute."); *see also id.*

at 1381 (affirming a decision where the special master found that the injury was caused by another condition "was the sole cause" of the injury, and declined to engage in a superseding cause analysis).

Even if the Special Master could have found a temporal relationship at prong three, the Special Master is correct that such a finding would have been of no moment to the causation analysis where, as here, the petitioner failed to satisfy other *Althen* prongs. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 206 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014) (citing *Althen*, 418 F.3d at 1278) ("[A]lthough probative, satisfaction of the third prong is insufficient, standing alone, to prove causation."). Accordingly, the Special Master did not err in finding that possible temporal proximity was insufficient to support causation, especially where he had already found that Petitioner's claim failed at prong two because she could not demonstrate that her asserted plausible theory had occurred.

III. *Althen* Prong Three

As noted, the Special Master discussed the possible temporal proximity at prong three, but he declined to rule on it, stating such a finding "would not necessarily" entitle Petitioner to compensation. *Miller*, 2024 WL 1340598, at *6–7. Petitioner claims the asserted temporal proximity between vaccination and onset of vasculitis compelled a finding that she satisfied prong three, and that the Special Master's refusal to rule on *Althen* prong three precluded Petitioner from the benefit of relevant circumstantial evidence of causation. Obj. Mem. at 1, 8. Respondent contends it is well-established that "[f]ailure to satisfy a single *Althen* prong is dispositive." Resp't Resp. at 10 (citing *La Londe*, 110 Fed. Cl. at 201 (2013)). Accordingly, Respondent claims the Special Master properly declined to rule on prong three because Petitioner's claim had failed at prong two. *Id.* at 10–11.

It is well-established that the Special Master was not required to decide prong three if he properly decided Petitioner failed at prong two. *See Henkel v. Sec'y of Health & Hum. Servs.*, No. 2023-1894, 2024 WL 3873569, at *1 (Fed. Cir. Aug. 20, 2024) ("Because we conclude that the special master's finding on *Althen* prong three was not arbitrary or capricious . . . and because Appellants needed to prevail on all three prongs to have their petition granted, we affirm the petition's denial without reaching the prong-two finding."); *Koehn v. Sec'y of Health & Hum. Servs.*, 773 F.3d 1239, 1244 (Fed. Cir. 2014) ("Because [petitioner] failed to meet her burden under the third *Althen* prong, however, and failure to do so under any one of the *Althen* prongs is dispositive of this case, the Special Master correctly denied [petitioner's] petition."); *Trollinger*, 167 Fed. Cl. at 142 (same); *Contreras v. Sec'y of Health & Hum. Servs.*, 107 Fed. Cl. 280, 295 (2012) (citing *Broekelschen*, 618 F.3d at 1350–51) ("[T]here is no *per se* rule forbidding a special master to deny compensation upon a finding that a petitioner has failed to meet one of the *Althen* prongs . . . ."); *see also Broekelschen*, 618 F.3d at 1344, 1351 (affirming the special master's decision where he determined the petitioner failed at prong one, and therefore declined to rule on prongs two and three); *La Londe*, 110 Fed. Cl. at 206 (affirming petitioner failed to prove causation where it failed at prongs one and two, but where the special master agreed "there was a clear temporal relationship").

The Special Master reasonably found that Petitioner failed to demonstrate causation at *Althen* prong two. *See supra* Discussion Section II. The Special Master was therefore not required to make a finding at *Althen* prong three.

The Special Master also reasonably found that possible temporal proximity was insufficient to establish causation. *See supra* Discussion Section II(B). Accordingly, the Special Master's

decision to forgo ruling on *Althen* prong three was well-founded and was not arbitrary or capricious.

CONCLUSION

At prong one, the Special Master reasonably concluded that only one of Petitioner's theories was supported by record evidence. At prong two, the Special Master reasonably concluded Petitioner failed to meet her burden to prove causation because the record evidence did not demonstrate the existence of immune complexes. At each step, the Special Master did not require a heightened burden of medical certainty; rather, he appropriately required that Petitioner establish both her immune complexes theory and causation by preponderant evidence. The Special Master was neither required to rule on prong three nor consider temporal proximity at prong two.

Therefore, the Court **DENIES** Petitioner's Motion for Review (ECF No. 125) and **SUSTAINS** the Decision of the Special Master. The parties are directed to **CONFER** and **FILE** a Notice within 14 days of this Memorandum and Order, attaching a proposed public version of this Sealed Memorandum and Order. The Clerk of Court is directed to enter judgment accordingly.

IT IS SO ORDERED.

Eleni M. Roumel

ELENI M. ROUMEL
Judge

September 3, 2024
Washington, D.C.